510(k) Summary K131064

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SEP 0 4 2013

August 19, 2013

Contact: Kichul Cha, CEO

1. **Identification of the Device:**
   Proprietary-Trade Name: BPBIO320 and BPBIO320n
   Common/Usual Name: Blood pressure monitor
   Classification Panel: Cardiovascular
   Classification Names: Non-invasive blood pressure measurement system
   Classification: II, Product Code: DXN

2. **Equivalent legally marketed devices:**
   (Predicate device Information)
   A&D Engineering Inc. Digital Blood pressure monitors Model TM2655P (K010828)

3. **Indications for Use (intended use)** The Biospace blood pressure monitor is designed to measure blood pressure (diastolic and systolic) and pulse rate in adult patients with arm circumference range between 17cm - 42cm. (BPBIO320n is the same device as the BPBIO320 and has same specifications except it has no printer module.)

4. **Description of the Device:**
   BPBIO320/BPBIO320n is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff size is 545 × 120 (mm) and the arm circumference range is between to 17cm - 42cm. BPBIO320/BPBIO320n is designed and manufactured according to ANSI/AAMI SP10 manual, electronic or automated sphygmanometers. BPBIO320/BPBIO320n can measure systolic, diastolic pressure and pulse rate on the principle of oscillometric on inflation. The oscillometric method detects volume displacements within the artery and senses pressure variations within the blood pressure cuff during inflation.

5. **Safety and Effectiveness, comparison to predicate device.**
   The testing results indicate that BPBIO320/BPBIO320n is as safe and effective as the predicate device.

6. **Summary of technological characteristics of the device compared to the predicate device.**BPBIO320/BPBIO320n is intended to be used in measuring human systolic, diastolic and

pulse rate by oscillometric method. Performance characteristics are in accordance with ANSI/AAMI SP10:2002/ (R) 2008. The substantial equivalence between BPBIO320/BPBIO320n and TM2655P can be evaluated from several aspects as listed in below table.

Item	Proposed device BPBIO320/BPBIO320n	Predicate device TM2655P	Similarities	Differences
Device Classification	Class II	Class II	Equivalent	Negligible
Classification Panel	Cardiovascular	Cardiovascular	Equivalent	Negligible
Intended Use (Indications for use)	Monitor non-invasive blood pressure and pulse rate	Monitor non-invasive blood pressure and pulse rate	Equivalent	Negligible
Anatomical sites	Upper arm or limb	Upper arm or limb	Equivalent	Negligible
Device Description				
Technology-measurement methodology	Oscillometric measure upon inflation	Oscillometric measure upon deflation	Different	SP10 and safety standards were met. Clinical test according to the SP10 was met.
Energy used	AC	AC	Equivalent	Negligible
Weight	9kg	9kg	Similar	Negligible
Dimensions	489(W)x409(L)x284(H) mm	245(W)x320(H)x390(D) mm	Similar	Negligible
Descriptive characteristics				
Inflation & deflation	Automatic control	Automatic control	Equivalent	Negligible
Display	LED	LED	Similar	Negligible
Parameters	SYS, DIA, PULSE RATE	SYS, DIA, PULSE RATE	Equivalent	Negligible
System output	RS232-compatible; digital; mini-din connector	RS232-compatible; digital; mini-din connector	Equivalent	Negligible
Performance specifications				
Standards met	ANSI/AAMI SP-10, IEC-60601-1, IEC60601-1-2	ANSI/AAMI SP-10, IEC-60601-1, IEC60601-1-2	Equivalent	Negligible
Operating environment	10~40℃ (50~104°F), 30~75%RH; 70~106kPa	10-40 °C, 85%RH or less, non condensing	Similar	Negligible
Storage environment	-20~70℃ (-4~158°F), 10~95%RH, 50~106kPa (No condensation)	-20 to 60 °C, 95%RH or less, non condensing	Similar	Negligible
Measurement range	Blood pressure : 40~300mmHg, Pulse rate : 30~240bpm	Blood pressure : 10~280mmHg Pulse rate : 30~200bpm	Similar	Negligible
Accuracy	Pressure : ±3mmHg Pulse rate : ±2%	Pressure : ±3mmHg Pulse rate : ±5%	Equivalent	Negligible

7. **Determination of Substantial Equivalence is based on as assessment of performance data**

Non-clinical tests have been done as follows:
Electromagnetic compatibility test according to IEC 60601-1-2
Electrical Safety test according to IEC 60601-1
FCC test according to FCC part 15
Safety and performance characteristics test according to ANSI/AAMI SP10

None of the tests demonstrate that BPBIO320/BPBIO320n raises new questions of safety and effectiveness.

8. **Clinical Test concerning the compliance of ANSI/AAMI SP10**
Compared to deflation detection of predicate device TM2655P (K010828), BPBIO320/BPBIO320n is an inflation detection device, so the arithmetic is changed. As a result, a new clinical test is done in accordance with ANSI/AAMI SP10, and the device met all applicable requirements of the standard.

9. **Harmonized standards summary**
BPBIO320/BPBIO320n conforms to the following standards:
   - IEC 60601-1:1990 + A1: 1993 + A11: 1993 + A12: 1993 + A2: 1995 + A13: [1996] Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (= IEC 60601-1:1988 + A1+ A2+corrigendum, mod.)
   - IEC 60601-1-2 [2007] Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility Requirements and tests (IEC 60601-1-2:2007 (Modified))
   - IEC 62304 [2006] Medical device software, Software life-cycle processes
   - ISO 14971 : 2009 Risk Management Process
   - ANSI/AAMI SP10 : 2002/ (R) 2008 & ANSI/AAMI SP10 : 202/A1 : 2003/ (R) 2008 & ANSI/AAMI SP10:2002 /A2 : 2006/ (R) 2008

10. **Comparison to the predicate device and the conclusion**
BPBIO320/BPBIO320n is substantially equivalent to the TM2655P whose 510(k) number is K010828. The devices are identical in intended use, and very similar in the design principles, the performance and the applicable standards. Only their appearance, the user interfaces are different. The measurement process is different, that is BPBIO320/BPBIO320n will get the measurement results when the device is inflating, while TM2655P gets the result during the deflating period. However the test in this submission provides demonstration that these small differences do not raise any new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

September 4, 2013

Biospace Corporation Limited
C/O Daniel Kamm
8870 Ravello Ct
Naples, FL 34114 US

Re: K131064
Trade/Device Name: Biospace Blood Pressure Monitor, Models BPBIO320 and BPBIO320n
Regulation Number: 21 CFR 870.1130
Regulation Name: Automated Non-Invasive Blood Pressure Meter
Regulatory Class: Class II
Product Code: DXN
Dated: July 22, 2013
Received: April 16, 2013

Dear Daniel Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131064

Device Name: Models BPBIO320 and BPBIO320n

Indications for use:

The Biospace blood pressure monitor is designed to measure blood pressure (diastolic and systolic) and pulse rate in adult patients with arm circumference range between 17cm - 42cm. (BPBIO320n is the same device as the BPBIO320 and has same specifications except it has no printer module.)

Prescription Use (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.09.04 10:07:31 -04'00'